



MARYLAND Department of Health

Wes Moore, Governor • Aruna Miller, Lt. Governor • Laura Herrera Scott, M.D., M.P.H., Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

Neil Leikach, Board President • Deena Speights-Napata, Executive Director

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name _____
Street Address _____
Business Telephone Number _____ Business Fax Number _____
Inspection Date: _____ Arrival Time _____ Departure Time _____
Type of Inspection: Annual Follow-up Previous Date: _____
Name of Inspector: _____

1. GENERAL INFORMATION

Yes No

- The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment.

Pharmacy Hours: _____

- All permits, licenses, and registrations are posted conspicuously.
HO § 12-311, HO § 12-408(b) and HO § 12-6B-08

Maryland Pharmacy Permit Number _____ Expiration Date: _____

CDS Registration Number _____ Expiration Date: _____

DEA Registration Number _____ Expiration Date: _____

- The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19
- The pharmacy provides services to Long Term Care facilities or assisted living facilities. (If yes, complete Long Term Care Inspection Form) COMAR 10.34.23

Yes No

- The pharmacy fills original prescriptions received via the internet.
- The pharmacy fills original prescriptions via e-prescribing.
- The pharmacist fills mail order prescriptions.

If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07

Comments: _____

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws

| Pharmacist Employees | License # | Exp Date |
|----------------------|-----------|----------|
| | | |
| | | |
| | | |

(Attach list if necessary)

| Registered Technicians | Registration # | Exp Date |
|------------------------|----------------|----------|
| | | |
| | | |
| | | |
| | | |
| | | |

(Attached list if necessary)

| Unlicensed Personnel (non-registered) | Title | Duties |
|---------------------------------------|-------|--------|
| | | |
| | | |
| | | |
| | | |

(Attach list if necessary)

3. PERSONNEL TRAINING

Yes No

- There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03 and 10.34.21.05
- All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B(3) and (4)

Yes No

- Maintaining records
- Patient confidentiality
- Sanitation, hygiene, infection control
- Biohazard precautions
- Patient safety and medication errors COMAR 10.34.26.03

Comments: _____

4. SECURITY COMAR 10.34.05

Yes No

- The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)
- The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)
- The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)

Comments: _____

5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes No

- Pharmacy area is clean and orderly. HO § 12-403(b) (11) (ii)2.
- The pharmacy provides a compounding service (non-sterile procedures).

Yes No

- If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02

Yes No

- The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
- The pharmacy has hot and cold running water.
- The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
- The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP COMAR 10.34.07.01B

Temperature _____

- The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature _____

- If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.

Temperature _____

- The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)
- The pharmacy has online resources. HO § 12-403(b)(15)

Comments: _____

6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No

- Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)

The following label requirements are met if a drug is dispensed pursuant to a prescription:

HO § 12-505

Yes No

- The name and address of the pharmacy; HG § 21-221(a)(1)
- The serial number of the prescription; HG § 21-221(a)(2)
- The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3)
- The name of the prescriber; HG § 21-221(a)(4)
- The name of the patient; HG § 21-221(a)(5)(i)
- The name and strength of the drug or devices; HO § 12-505(c)
- The directions for use; HO § 12-505(b)(2)(ii) and HG §21-221(a)(5)(ii)
- The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii)
- The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)
- The expiration date is indicated; HO § 12-505(b)(2)

Yes No

- The pharmacist and data-entry technician initials are on prescriptions. COMAR 10.34.08.01
- Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

Comments: _____

7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes No

- There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider. COMAR 10.34.26.02
- The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B
- There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

Comments: _____

8. CONFIDENTIALTY

Yes No

- Confidentiality is maintained in the creation, storage, access disposal and disclosure of patient records. HO § 12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations
- Any identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG §4-301 through §4-307. COMAR 10.34.10.03B

Comments: _____

9. INVENTORY CONTROL PROCEDURES

Yes No

- The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR10.34.24.03
- The pharmacy has a procedure in place for removal of all expired drugs (both prescription and OTC). COMAR 10.34.12.01

Comments: _____

10. CONTROLLED SUBSTANCES

Power of Attorney _____

Yes No

- The pharmacy has a record of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B
Inventory date: _____
- Biennial Inventory completed at Opening or Closing (circle one)
- The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
- Records are kept of all receipts of controlled substances entered into the pharmacy inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05
- There are written policies and records for return of CII, CIII-V.
- Hard copy or electronic prescription files are maintained chronologically for 5 years.
- Schedule II controlled substances are dispersed throughout the stock of non-controlled substances or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)
- All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)
- The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)

Comments: _____

11. AUTOMATED MEDICATION SYSTEMS Yes No (if No, go to #12)

Yes No

- The facility uses an automated device(s) as defined in COMAR 10.34.28.02.
Policies and procedures exist for (check all that apply): COMAR 10.34.28.04A

Yes No

- Operation of the system
 - Training of personnel using the system
 - Operations during system downtime
 - Control of access to the device
 - Accounting for medication added and removed from the system.
-
- Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safe guards. COMAR 10.34.28.06

 - Adequate records are maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes No

- Maintenance records.
 - System failure reports.
 - Accuracy audits.
 - Quality Assurance Reports.
 - Reports on system access and changes in access.
 - Training records.
-
- Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B
 - The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments: _____

12. OUTSOURCING Yes No (if No, go to #13)

Yes No

- The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
- The facility serves as a secondary pharmacy. COMAR 10.34.04.02
- The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.
If yes: Name of agency, state of incorporation, service contracted, and State of Maryland
License/Permit Number: COMAR 10.34.04.06E

Comments:

- The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)

If the pharmacy outsources a prescription order:

- The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
- Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner: COMAR 10.34.04.06 (Check all that apply)

Yes No

- That the prescription order was prepared by a secondary pharmacy.
- The name of the secondary pharmacy.
- The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
- The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
- The date on which the prescription order was transmitted to the secondary pharmacy.
- The date on which the medication was sent to the primary pharmacy.

Yes No

- The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F
- The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes: COMAR 10.34.04.07 (Check all that apply)

Yes No

- That the prescription order was transmitted from another pharmacy.
- The name and information identifying the specific location of the primary pharmacy.
- The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
- The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
- The date on which the prescription order was received at the secondary pharmacy.
- The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

13. Recommended Best Practices:

Yes No

- A perpetual inventory is maintained for Schedule II controlled substances.
- There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
- The pharmacy has written policies and procedures for the safe handling of drug recalls.
See www.recalls.gov
- The pharmacy maintains records of all recalls. See www.recalls.gov

Inspectors Comments:

Inspector Signature _____

Pharmacist Name ((Print): _____ **Date:** _____

Signature:
